REMARKS/ARGUMENTS

This Amendment accompanies a Request for Continued Examination and addresses the issues raised in the Official Action of August 15, 2008, a Final Rejection.

Counsel notes that neither this Official Action nor the previous one acknowledged the existence of claims 54-56. These claims were added in the Preliminary Amendment of February 14, 2005 and remain active in the present application and are directed to elected subject matter.

Further, counsel notes that in the Office Action Summary claims 53-56 and 69 are not allocated as either being claims withdrawn from consideration. They should not be as they are directed to elected subject matter or as rejected claims. (Although claims 53 and 69 are mentioned in the main portion of the Official Action.) It is requested that claims 54-56 be examined on the merits during the processing of this Request for Continued Examination.

Claim 40 is amended in order to more particularly point out and distinctly claim that which applicant regards as his invention. The significance of this Amendment and basis for it in the original description will be apparent from the remarks that follow.

The Examiner's Action of September 15, 2008 reiterates objections based on U.S. 5,922,560 to Jacobsen arguing that it does disclose emulsions as cells that might be ruptured and astaxanthin released. Jacobsen does, in general, teach the exact opposite of the present invention that astaxanthin is bioavailable from whole yeast cells. The reality is that this is not correct and much better bioavailability is achieved when you remove the astaxanthin from the yeast cell, emulsify the astaxanthin separately and use it as a fish feed.

In short, the claims define an invention that is the exact opposite of Jacobsen.

Let us firstly consider the issue of whether an emulsion forms. Jacobsen prepares mutant yeast cell strains that over produce astaxanthin. The Examiner notes in column 9 line 25, that the emulsifier, oil phase and antioxidant can be added to the yeast cream before drying or after drying or indeed some components can be added before and some after drying. Note however that whatever order the additional components are added in, what is formed in that addition is eventually or already dried, i.e. any water removed. The material which is eventually formed in Jacobsen is a dry, i.e. water free. There is clearly no intention to manufacture a stable emulsion in Jacobsen as the final material which Jacobsen targets is always free of a water phase and cannot possibly be an emulsion.

Should it be argued that an emulsion is transiently formed before being dried applicant does not believe that can occur as the yeast cell is so massive that it cannot be emulsified. Responsive to an argument that there is no requirement in claim 1 for the astaxanthin to be emulsified only that an emulsion is formed, claim 40 is above amended to specify

"....wherein all the astaxanthin is in the form of micelles".

Claim 44 covers this possibility as it mentions that the fat soluble contents are in the form of micelles. Astaxanthin is fat soluble so it is not added matter by making this change. The examiner will note also page 6, line 2 where the possibility of the carotenoids being in the form of micelles is discussed.

This unquestionably distinguishes the claims over emulsions in which there is a yeast cell containing astaxanthin present. The astaxanthin cannot be present as a micelle when it is still present within the yeast cell.

The Examiner also argues that there might be anticipation of claim 1 since ruptured yeast cells might exude astaxanthin which could then be emulsified by the emulsifying agent before drying. The Examiner argues that the blending process might rupture the cells.

It is noted that at the bottom of column 9, there is discussion of an embodiment in which cells are deliberately ruptured during the drying process. There is also discussion of drying without rupturing. If it is necessary to rupture or prevent rupture during drying that is an implication that blending does not cause rupture. If blending caused rupture there would be no cells to rupture or prevent rupture of in the composition being dried. No support is seen for the Examiner's position that blending causes rupturing on the yeast cells.

The Examiner might argue that during the drying step rupture occurs and there again would be a transient emulsion when astaxanthin is released from the cells but before all water is removed. There is again, no support for that position but in any event revised claim 40 requires all the astaxanthin present to be in the form of micelles. Where there was a cell present containing astaxanthin as well as some free astaxanthin, not all the astaxanthin would be in the form of micelles so there would not be overlap with claim 40.

These arguments and amendments of claim 40 resolve and overcome the novelty rejection.

Turning to non-obviousness and the three rejections based on this ground, applicant reiterates many of the points that have made before. The whole point of the instant patent application is actually to overcome the problems of astaxanthin bioavailability which Jacobsen's suggestions cause. Where the astaxanthin is still in the cell wall of a yeast, it is very poorly bioavailable. Unless the cell wall of the yeast organism is mechanically destroyed or chemically destroyed, the astaxanthin is simply not accessible to a fish or other marine organism.

One of the major benefits of using an emulsion of isolated (or synthetic) astaxanthin is that the small liposomes/micelles formed can integrate with the fat in the marine organism's diet and can therefore become very bioavailable. The inventor has found that at 4 or 5 ppm concentrations, his emulsion is much more bioavailable than a product based on a whole cell organism containing ten times that amount of astaxanthin. The reason is believed to be that the whole cell yeast is simply to large to integrate into the fat of the marine organisms diet. It is consumed only, perhaps, as a sprayed on additive to pellets and eaten therefore as a whole cell organism. This does not make astaxanthin bioavailable as it is wrapped up in the cell wall.

Many fish feeds are based on absorption of astaxanthin. Again, the use of a whole cell yeast containing the astaxanthin makes it impossible for any of that astaxanthin to be absorbed by anything. The particle size is simply too big for absorption. In contrast, the emulsion of the present invention is homogeneous (it's an emulsion) and can be absorbed by micro-organisms in a fish feed or even by the fish itself as the particle sizes are so small. Again, this shows that the bioavailability of the present emulsion is infinitely better than a whole cell product.

In fact, whole cell astaxanthin products are no longer sold in the industry as their bioavailability is so poor. In a study carried out in an aquarium in Dubai, a product based on a whole cell organism (Haematoccocus rather than Phaffia but the particle size is the same) where found to give no benefit to the fish. The fish lost color. When this whole cell product was replaced by the composition of the present invention, the fish regained normal color in 2 weeks.

The applicant knows therefore that the composition described in Jacobsen is not and cannot be an emulsion where all the astaxanthin is in the form of micelles.

The Examiner has previously argued that the Jacobsen disclosure encompasses micelles as these are regarded as forming spontaneously. Micelles cannot form around a whole yeast cell

and all the astaxanthin in Jacobsen is not in the form of a micelle. Even with rupture some must still be in the cell.

This invention essentially concerns a food product for marine animals, in particular fish. It is very difficult to ensure that fish outside of their natural environment get all the nutrients they need to flourish. As noted in the present application and by Jacobsen, astaxanthin has been found to be a critical part of the diet of these organisms and the skilled person has to devise ways of getting the astaxanthin to the fish in sufficiently high dosages.

The present invention is primarily about increasing the bioavailability of astaxanthin over a composition such as that of Jacobsen. Jacobsen attempts to improve bioavailability by increasing the astaxanthin content in a yeast to incredibly high levels. What Jacobsen does not realize is that the problem of bioavailability is associated with the form of the astaxanthin, i.e. the fact that it is present in the cell wall of a whole cell organism, rather than the concentration thereof. The amount of astaxanthin naturally in yeast would have a useful effect on a marine organism if it could actually be given to the organism in an accessible form. The present invention therefore solves the problem of bioavailability by providing the astaxanthin in the form of a micelle. This is a completely different solution from Jacobsen who attempts to solve the problem by providing whole cell organisms with so much astaxanthin that a bio effective dose can be extracted by the marine organism.

The present solution has numerous benefits. Firstly, it allows the amount of astaxanthin to be altered to any desired level. Different marine organisms need different levels of astaxanthin. With applicant's emulsion, the amounts can be varied precisely by adding more or less of the active material. That is not an option when you are using a whole cell yeast. When using a whole cell, the astaxanthin concentration is what is naturally in the cell.

Moreover, the amounts of astaxanthin used can be much lower when it is provided in the highly bioavailable emulsion form as this oily composition is able to integrate into the fatty parts of fish feed and is therefore readily available to the marine organism when the feed is eaten.

As is clear from the examples of the present invention high levels of astaxanthin in the fish feed are achieved using the composition of the invention. In Example 1, the astaxanthin content is 0.05% (lucantin pink is synthetic astaxanthin) in the feed product, i.e. around 500 ppm. This is then diluted a 4kg/400L, so by 100 times. The total astaxanthin content of the feed of the

invention is around 5 ppm. The inventor's results show a significant increase in astaxanthin content in the shrimp feeds in the examples. Note that the whole yeasts of Jacobsen have at least 3000 ppm of astaxanthin!

As noted above, applicant's emulsion can be absorbed by microorganisms as well as eaten by shrimp and the like. No whole cell product can be absorbed.

The present invention therefore offers a completely different solution to the problems of astaxanthin bioavailability than is offered by Jacobsen. Jacobsen does not teach emulsions and whole cells cannot be emulsified. Whole cells suspensions sediment and do not emulsify. In no way therefore does Jacobsen appreciate that astaxanthin bioavailability can be hugely improved if you take it out of the cell and emulsify it.

The Examiner considers the combination of Jacobsen and Yokoyama (JP408269079) as this document describes the use of a glucoside of astaxanthin as a color improver for fish. Yokoyama is not relevant to the claims as no emulsion is described therein.

Applicant does not now address the objections based on Wein, Burkwall or Dartey (but reserves the right to do so) as applicant does not presently intend to rely on the nature of emulsifier, stabilizing agent or preservative as giving patentability. These objections are therefore moot.

Filed concurrently herewith is an Information Disclosure Statement. Please consider the documents identified in this IDS during further processing of this application.

Respectfully submitted,

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